Navy Medicine

esearch and Development Executive Boa

(REDEB)

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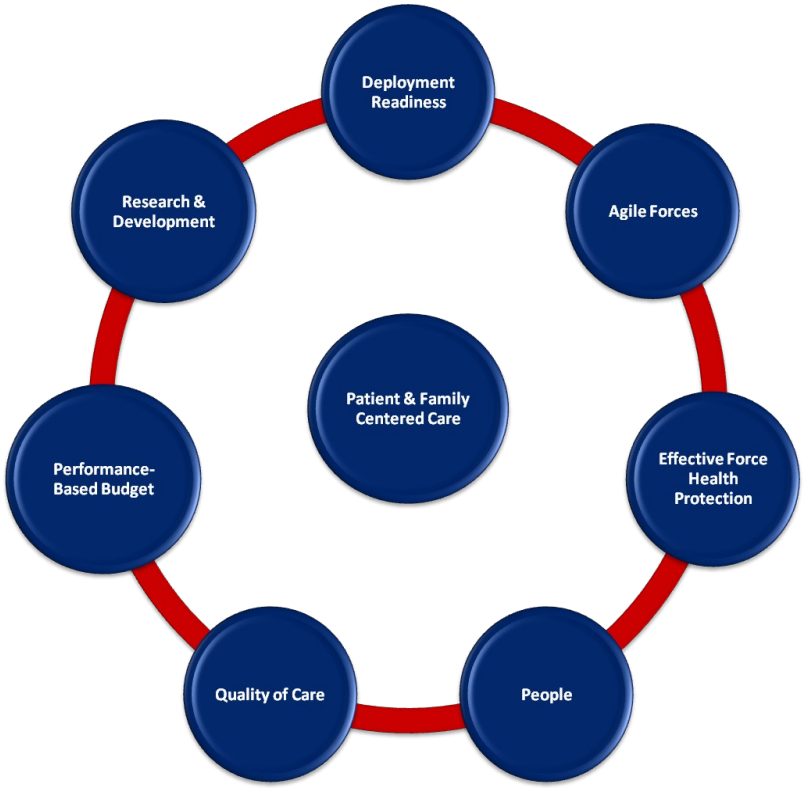
Navy Medicine Strategic Goals



Research and Development - *Navy Medicine will conduct relevant research, development, testing, evaluation & clinical investigations which protect & improve health of those in our care.*

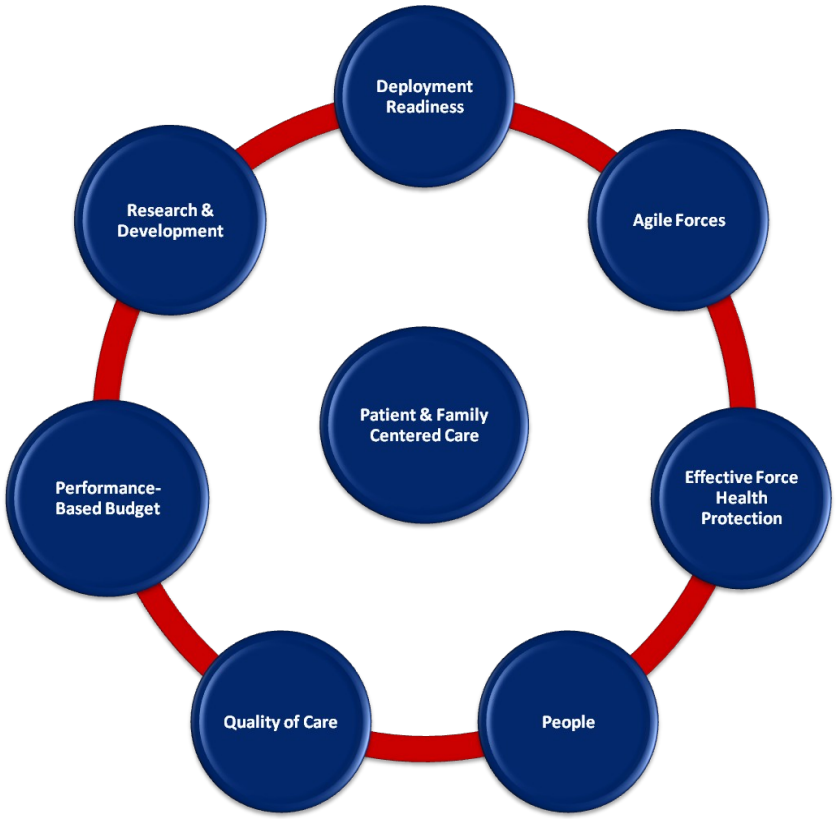
Effective Force Health Protection - *Navy Medicine will promote healthy Naval Forces and ensure Warfighters are medically prepared to meet their mission.*

Deployment Readiness - *Every uniformed member of Navy Medicine will be fully deployable based on successful achievement of all training, administrative and medical readiness requirements.*

Agile Forces - *The Naval Forces will have the right capabilities to deliver consistent, appropriate and timely health care services across the entire range of joint military operations.*

Quality of Care - *Navy Medicine health services outcomes meet or exceed patient quality expectations. Our providers deliver the best & current practice complemented by convenient access, lasting results, preventive health & mitigation of health risk.*

Navy Medicine Strategic Goals



People - *Navy Medicine will maintain the right workforce to deliver medical capabilities across the full range of military operations through the appropriate mix of accession, retention, education and training incentives.*

Performance-Based Budget - *Performance-Based Budgeting transforms Navy Medicine from historically based fiscal planning & execution into a process linking resources to performance goals. This properly aligns authority, accountability & financial responsibility with the delivery of quality, cost effective health care.*

Patient and Family-Centered Care - *Patient & Family-Centered Care is Navy Medicine's core concept of care. It identifies each patient as a participant in his or her own health care & recognizes the vital importance of the family, military culture & the chain of command in supporting our patients*

Secretary of Defense Memo
26 June 2008

Subject: **Caring for Our Wounded Personnel and Their Families**

[Paragraph (3) “Medical Related Research”]

“The Department funds billions of dollars of medical research annually fo
a variety of purposes. Some of this goes for research of ***tenuous benef***
[italics supplied] to our military population.”

“…I request the development of a tailored plan to provide R&D investme
that advance state of the art solutions for world class medical care with a
emphasis on … conditions directly relevant to the injuries our soldiers are
currently receiving on the battlefield.”

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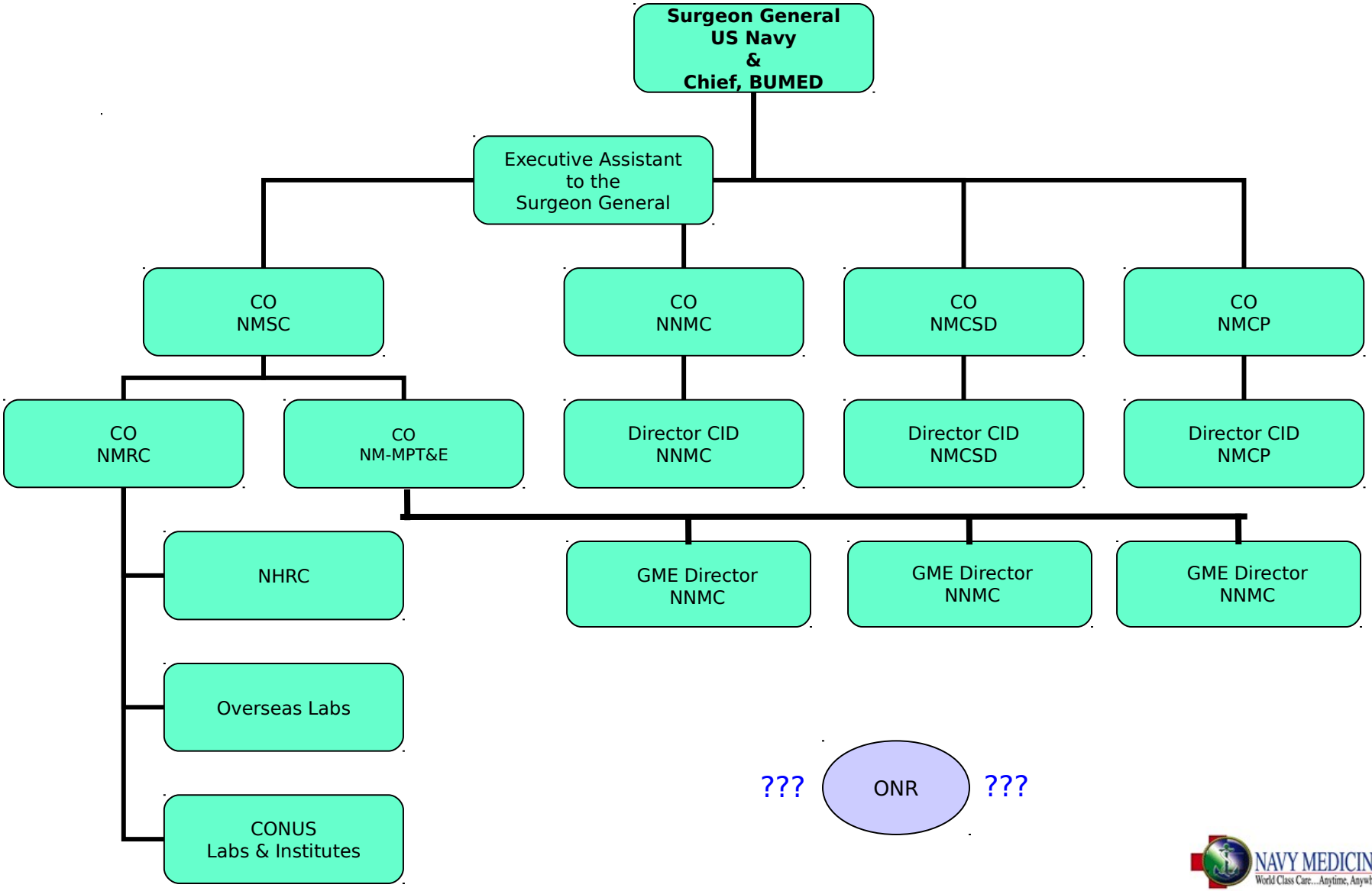
Navy Medicine Research



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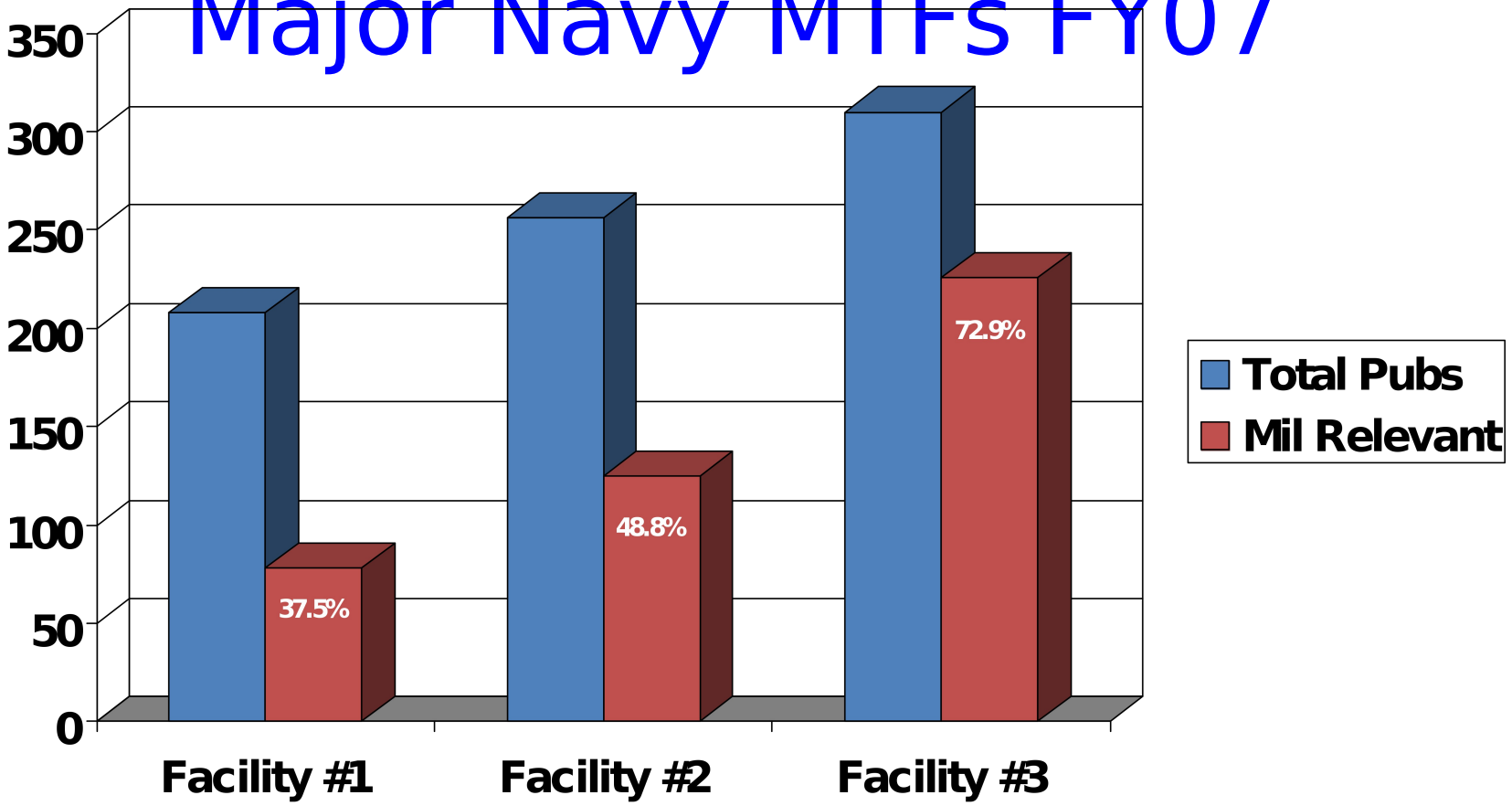
"Militarily Relevant" Research Pubs
Major Navy MTFs FY07



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Research and Development Executive Board (REDEB)

- REDEB serves as the Surgeon General's executive strategic leadership body for policy, oversight, quality improvement, and ongoing planning/development of research and research-related activities conducted within, sponsored by, or engaged by Navy Medicine activities and personnel.

- With the Office of Naval Research, line leadership, and other military medical departments, REDEB assists the Surgeon General and Navy Medicine with integration of research programs/assets within and outside Navy Medicine to accomplish its healthcare and readiness mission.

- REDEB Serves as a major voice that advises the Chief of the BUMED on research within DON and Navy Medicine.

Research and Development Executive Board (REDEB)

Core Members:

•Special Assistant for Research Program Integration and Mission Development; [Malone]

•Special Assistant for Clinical Research; and Director, Clinical Investigations Program [Cheatham]

•Special Assistant for Research Protections; and Director, Department of the Navy Human Research Protections Program [Richard]

•Special Assistant for Ethics and Professional integrity; and Director, Research Integrity Program Network [Gabriele]

Adjuncts: Other leaders or Special Assistants as needed.

Organizational Alignment: Reports directly to the Surgeon General via the Executive Assistant to the Surgeon General.

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Operations – REDEB

- Represents SG (R&D CEO) as his Executive Board to MTF's, R&D labs, extramural awardees etc.
- Integrates, synergizes, and promotes new research opportunities to augment Navy Medicine mission
- Integrates such efforts with ONR, USMC research, other federal and private sponsors etc.
- Responsible for strategic planning, future development, and direction for all research efforts and research assets, Commands, detachments etc.

Operations – REDEB

- Maintains individual duties/authorities as per specific and unique PDs, shares expertise/situational awareness, and integrates within membership as appropriate
- Meets regularly (direct meetings or teleconferences)
- Maintains ongoing colloquium with and within Board membership and with constituents
- During meetings, provides updates and reviews ongoing and new items for attention/action

Operations – REDEB

- Executes assigned taskers via REDEB Coordinator
- Assists regions/activities
- Provides regular updates and reports re: activities, accomplishments, challenges & horizons to the SG and regions via REDEB Coordinator and SG EA

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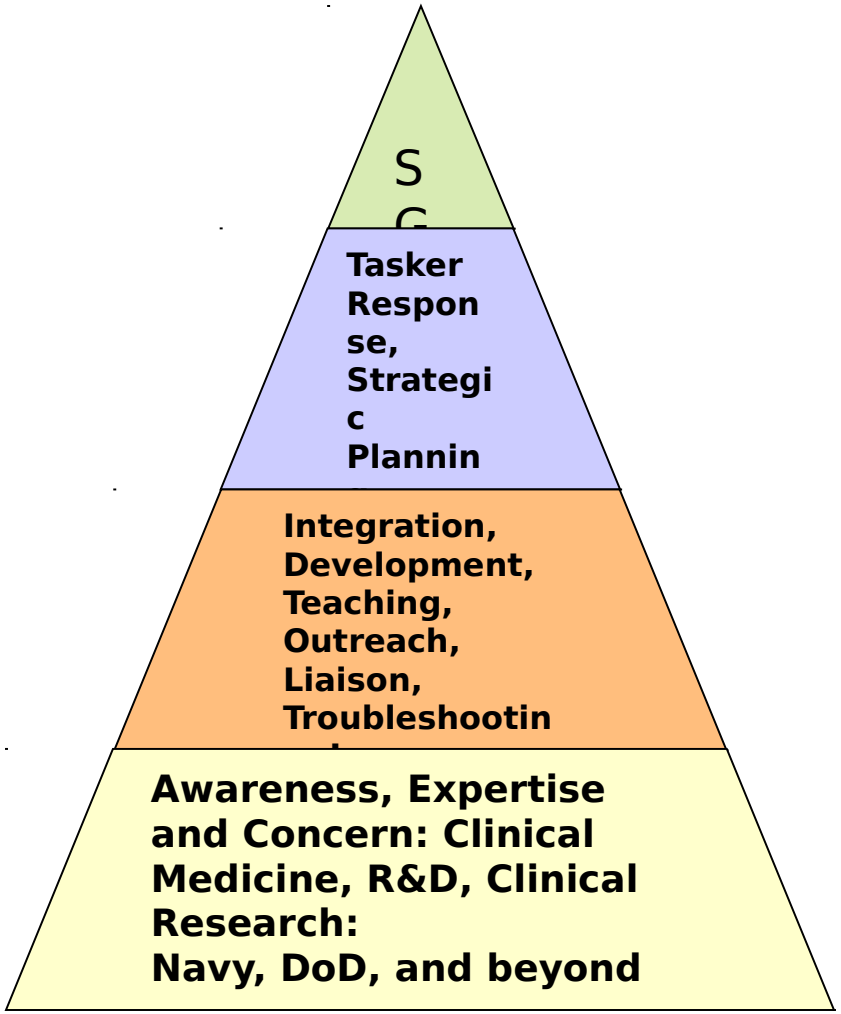
Graphic for Services


S
G
Tasker Respon se, Strategi c Plannin
Integration, Development, Teaching, Outreach, Liaison, Troubleshootin
Awareness, Expertise and Concern: Clinical Medicine, R&D, Clinical Research:
Navy, DoD, and beyond

Basic Duties

-Provides primary program analyses of submitted Medical Research initiatives for the BUMED claimancy. Researches, prepares and completes program analyses and provides findings/recommendations to the Surgeon General

-Provides recommendations and/or tasking responses to the Surgeon General with regard to Medical Research program issues as needed

-Works to facilitate creation of a team of at least three professional positions that together comprise a single voice that advises the Chief of the Bureau of Medicine and Surgery (BUMED) directly on the establishment and assessment of research undertaken within Navy Medicine

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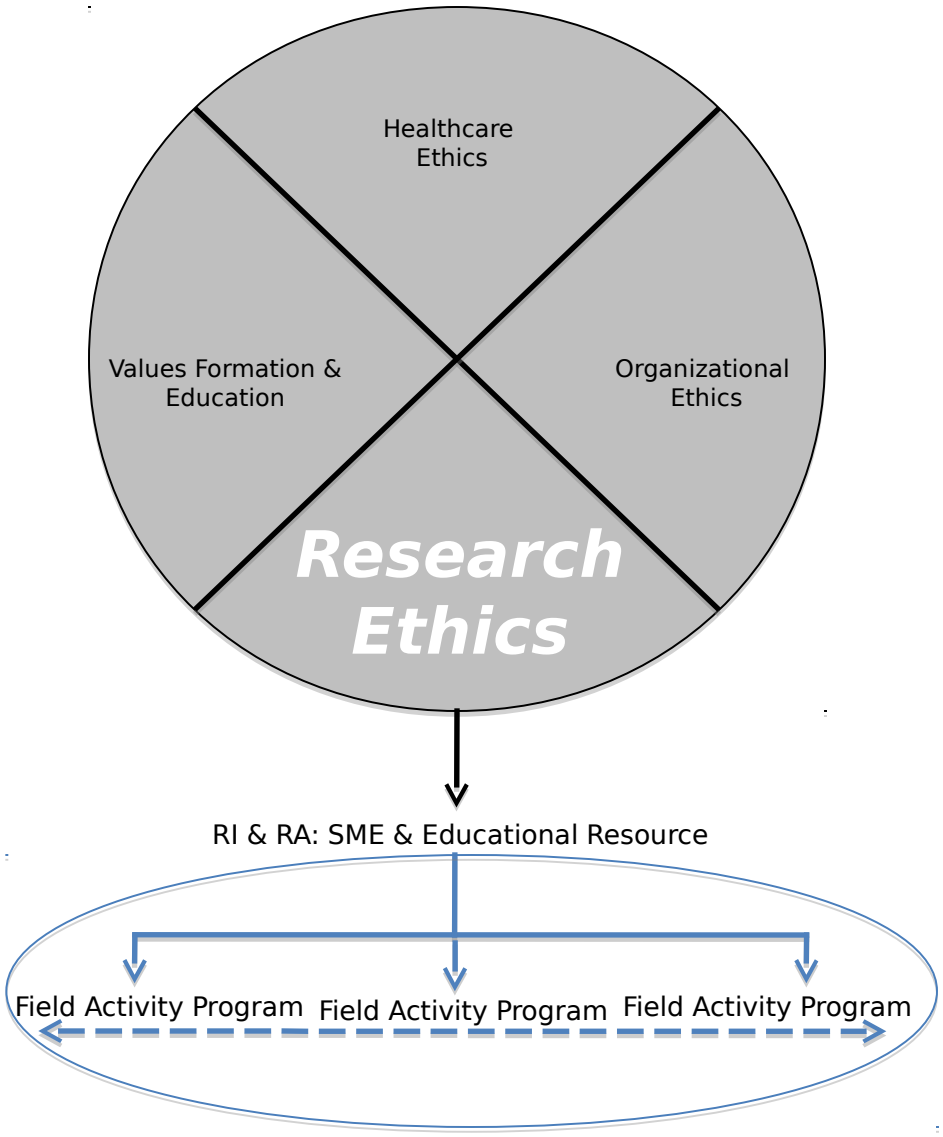
Special Assistant for Ethics and Professional Integrity (EPI)

EPI Service Map



Community Assistance/Services as:

- Ethics SME and policy formation assistant;
- SG's Executive Research Integrity Coordinator (ERIC);
- Local research integrity (RI) and research administration (RA) SME resource/asset;
- SG's local RI programs network coordinator;
- New research frontiers resource/concept developer;
- Responsible Conduct of Research (RCR) and
  RA education programs & resource/developer;
- Research misconduct processes resource;
- SG's POC for research misconduct reports to higher authority or extramural agencies;
- SG's networking officer with federal and private entities.

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DON HRPP: Background

2004
DDR&E inspected all DoD components' HRPP's

- **Designate single POA for Navy/Marine Corps HRPP**
- **Update HRPP policies**
- **Ensure all Navy/Marine Corps commands comply with federal / DoD / Navy regulations**

2005 – 2006
Navy Response

- **SG designated as single POA for HRPP**
- **Established DON HRPP (BUMED & ONR team)**
- **SECNAVINST 3900.39D signed 6 Nov 2006 – one policy for all Navy / Marine Corps**
- **2007 DDR&E report:** *"Navy senior leadership is extremely committed to a high caliber program that is highly regarded not only within DoD but also [among] the non-federal organizations."*

2007 – 2008
Status

- **2008 DDR&E report:** *"Navy has made significant progress in addressing findings…"*
- **<u>Full program</u>: Assurance reviews; site, assist, and training visits, and HQ-level post-approval reviews of protocols**
- **<u>Continuing Initiatives</u>: Conceptual Framework guide DON HRPP; DDR&E WG's for**

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Human Subject Research: Critical for Navy/Marine Corps

- Research involving human subjects is essential for optimizing warfighter performance:
  - Quantitative and Qualitative Research
  - Combat casualty care and management
  - Disease prevention and treatment, healthcare utilization
  - Aerospace and undersea medicine and research
  - Human factors engineering (Combat Information Center, aircraft displays, emergency egress systems, psychological effects, network formation)
  - Operator and weapon system integration
  - Protective clothing and devices development (IED protection, helmets, shipboard firefighting gear)
  - Midshipmen, recruit, and shipboard & submarine training

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DON HRPP Scope

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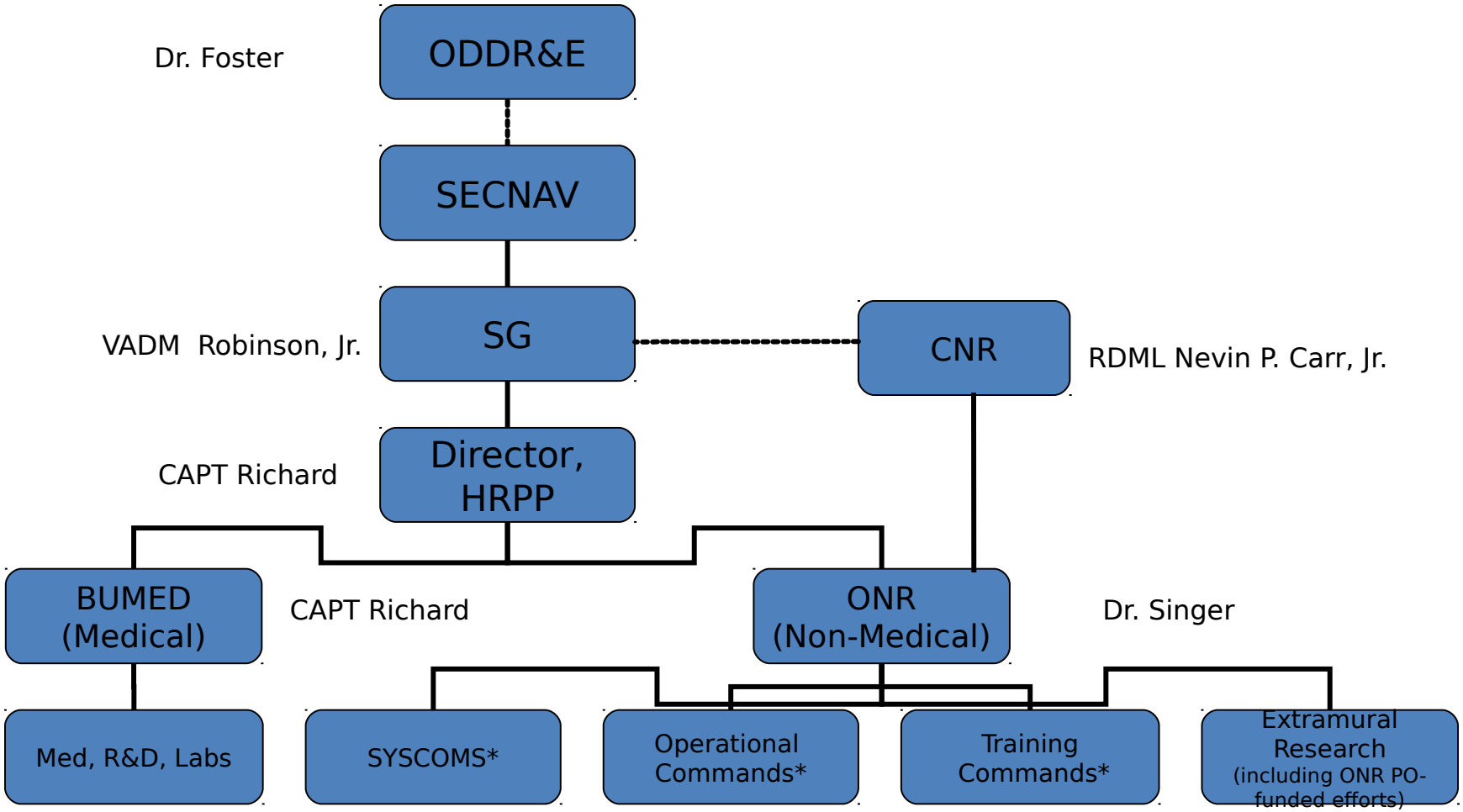
DON Human Research Protection Program



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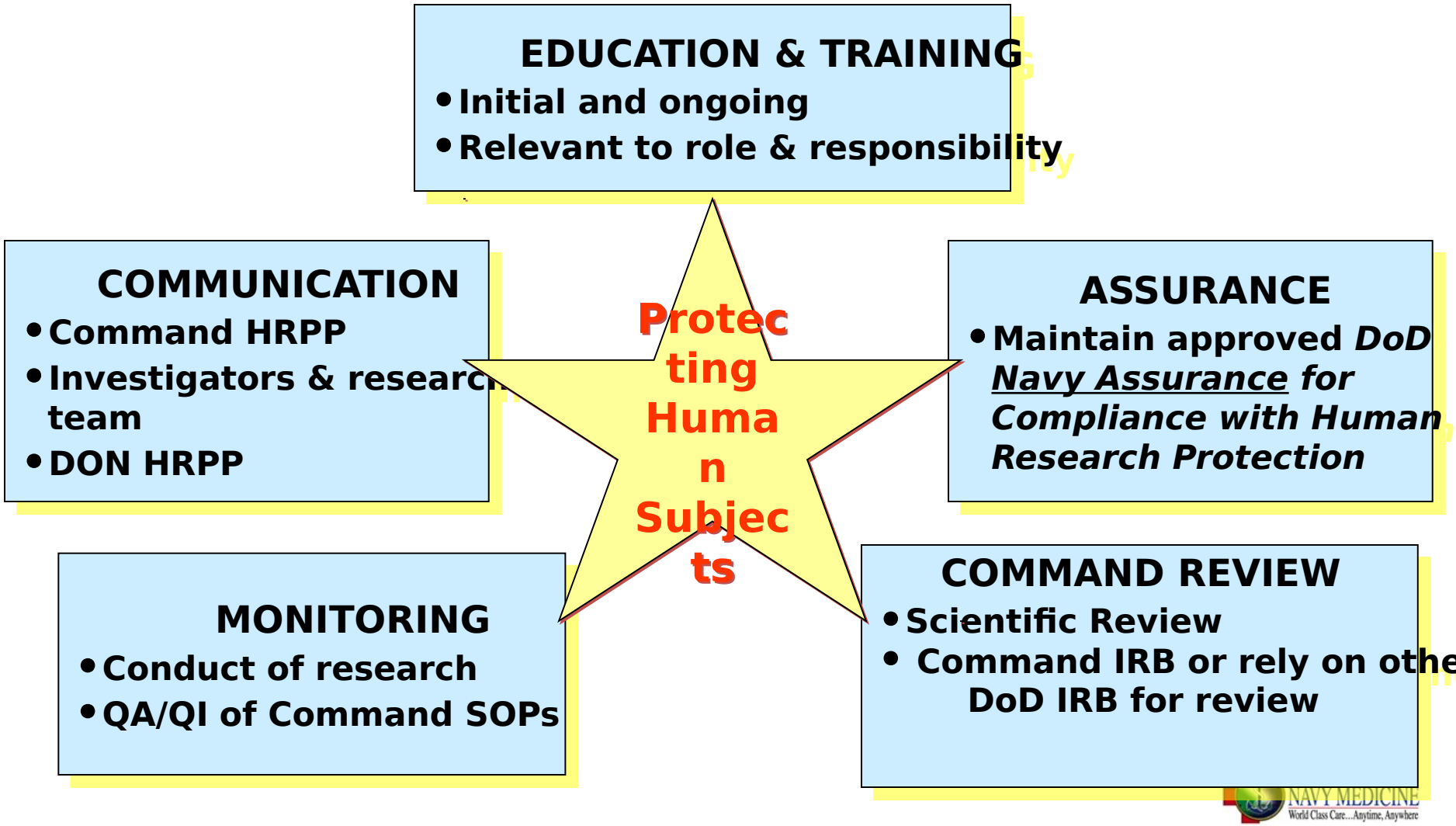
Key Responsibilities


EDUCATION & TRAINING
• Initial and ongoing
• Relevant to role & responsibility
COMMUNICATION
• Command HRPP
• Investigators & research team
• DON HRPP
Protecting Human Subjects
ASSURANCE
• Maintain approved DoD/Navy Assurance for Compliance with Human Research Protection
MONITORING
• Conduct of research
• QA/QI of Command SOPs
COMMAND REVIEW
• Scientific Review
• Command IRB or rely on other DoD IRB for review

Special Assistant for Research Protections and Director, DON HRPP

Services

Education & Training

Monitoring & Oversight

Community Outreach:
Communication

Policy/Assurance
Sustainment

Command Review & Presence

Basic Duties

Role: HRP (Navy & MC):

1. Executes/Maintains Enhances DON HRPP
2. Serves DON as DOD Component Human Research Protection
3. **Creates DON Culture Compliance & Excellence HRP**
4. Supports Human & Animal Research that is critical to mission for Navy and Navy Medicine

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Navy Clinical Investigation Program (CIP)

- Under Authority of DoD Instruction 6000.08
  - "Funding and Administration of Clinical Investigation Programs"
- Implemented by BUMEDINST 6000.12B *(currently draft)*
  - "Clinical Investigation (CI) Program (CIP) and Other Research Activities Supporting Graduate Medical Education (GME), Graduate Dental Education (GDE) and Graduate Professional Education (GPE)"

Navy Clinical Investigation Program (CIP)

- BUMEDINST 6000.12B *(draft)*
  - Graduate education programs utilized for:
    - **maintenance** of standard capabilities and proficiency
    - **development** of greater skills
  - Maintenance of operational force readiness:
    - **dependent on provision** of the highest standard of health maintenance and medical care resources
    - **Requires ensuring the education** and skill fitness of personnel who are to be expert in health and medical care delivery
    - **Requires serving the unique needs of Navy** operational forces in their broad elaboration
    - Therefore - **requires that post-basic learning and discovery** experiences of health care personnel be **tailored** to provide skills beyond what is available through standard medical, dental, nursing and allied health care training didactics

Navy Clinical Investigation Program (CIP)

- BUMEDINST 6000.12B *(draft)*
  - All teaching of applied skills and procedures have their origins in **fact and validated outcomes-based** experimentation and research
  - To be relevant and supportive of premier health maintenance and care delivery for Navy personnel and beneficiaries, the facts and validated outcomes provided in the graduate education experience provided by the Navy should
    - **include unique subject areas** of investigation
    - **be directed** toward not only **providing** an accredited educational experience, but one containing **specific skills** for provision of health care services to **operational personnel** and **beneficiaries**

Navy Clinical Investigation Program (CIP)

- BUMEDINST 6000.12B *(draft)*
  - **Research** is an **essential foundation** of **graduate** medical, dental, nursing and other allied health care **education**
    - in **teaching the value and method** of fact based discovery and translation of discovery to **outcomes based health care delivery**
    - As an **integral component** supporting provision of **premier "state-of-the-art"** health care in the **Navy**

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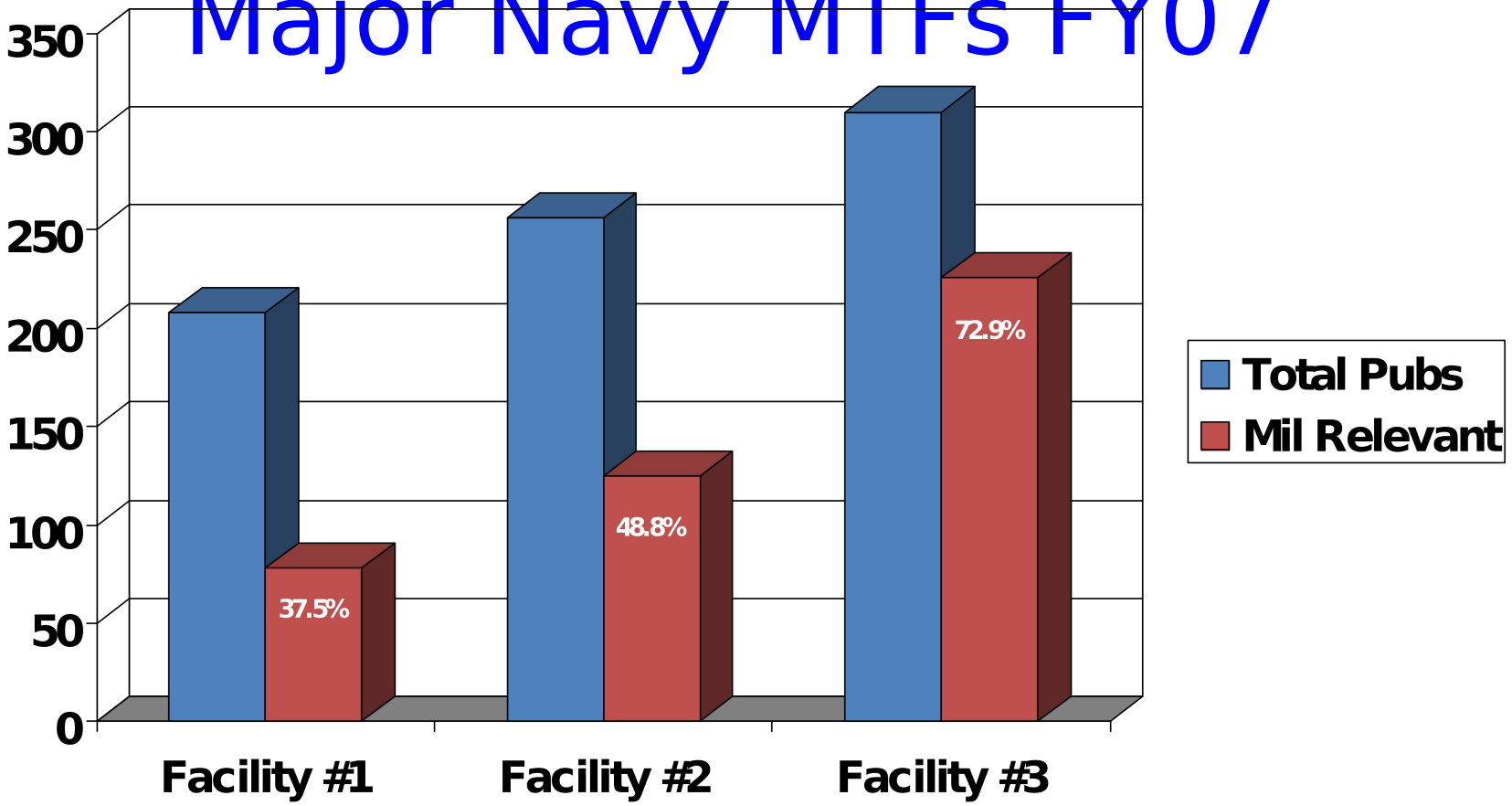
Navy Clinical Investigation Program (CIP)

- BUMEDINST 6000.12B *(draft)*
  - Research conducted at MTFs and DTFs:
    - Is **required for accreditation** of graduate medical and health science education programs
    - **Provides an environment of knowledge** acquisition and keen mental and skill development that supports an academic environment with high professional standing and parity with comparable civilian institutions
    - **Generates an atmosphere of scientific inquiry** essential to accommodate the development of new insights and technology that benefit the care of active duty personnel as well as dependent and retired beneficiaries
    - **supports health science education** and provides general contribution to knowledge
    - **Improves quality of care** for all health care beneficiaries

"Militarily Relevant" Research Pubs
Major Navy MTFs FY07



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DoD Clinical Investigation Program FY2007 Funding Summary

	ARMY	NAVY	AIR FORCE	USUHS
•FUNDS (K$)	44,226	5,695	9,966	80,400
•PROTOCOLS	2,395	667	520	318
PUBLICATIONS	646	552	122	349

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DoD Clinical Investigation Program
Funding FY-07

Funding Source	Amount	
	ARMY	Air Force Navy
Intramural (O&M DHP)*	$14,864,810	$51,000
Extramural – Other DoD and Federal Government	$4,856,742	$4,683,096
Extramural – Private Sector	$24,504,395	$961,289
TOTAL Funding	**$44,225,947**	**$9,966,000 $5,695,385**

* Does not include salary costs

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Army CIP Resources

	FY05	FY06	FY07	Change (FY06→FY07)
Funds--				
MEDCOM (P8)	$14,176,268	$14,174,028	$14,864,810	4.9%
Extramural	$23,196,134	$20,031,943	$29,361,137	46.6%
Total	$37,372,402	$34,205,971	$44,225,947	29.3%
Personnel--				
Officer	31	30	31	3.3%
Enlisted	27	26	21	-19.2%
DoD Civilian	95	102	97	- 4.9%

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FY07 Army GME Programs
(internships, residencies, fellowships)

	WRAMC	BAMC	MAMC	TAMC	EAMC	WBAMC	WAMC	Total
Programs	61	35	28	23	9	7	2	165
Staff as PI/AI	676	412	428	198	29	19	22	1,784
Trainees	386	257	231	210	72	62	31	1,249
Trainee as PI/AI	187	98	169	23	19	19	4	519
% of Trainees Conducting Research	48%	38%	73%					

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FY07 Navy GME Programs
(internships, residencies, fellowships)

MTF	#1	#2	#3					Total
Programs	14	42	31					87
Staff as PI/AI	?	231	226					457+
Trainees	258	257	354					869
Trainee as PI/AI	?	58	21					79+

% of Trainees Conducting Research	?%	23%	6%

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Special Assistant for Clinical Research & Director CIP
-- BASIC DUTIES [slide 1]

- Serves as the Special Assistant for Clinical Research and for the Clinical Investigations Program (CIP) of Navy Medicine

- Along with the SA for Research Programs & the SA for Research Protections, advises the Chief, BUMED directly on the establishment and assessment of research undertaken within Navy Medicine

- Provides the medical component to the overall BUMED research strategy

- Establishes the overall BUMED strategic vision for the CIP as part of a single research vision and strategy for Navy Medicine

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Special Assistant for Clinical Research & Director CIP -- BASIC DUTIES [slide 2]

- Performs preliminary reviews of research proposals and preliminary analyses of data from a sample of research and clinical protocol proposals to ensure:
  - scientific, medical and mission value
  - compliance with generally accepted principles and guides
  - adequacy of funding and infrastructure

- Establishes procedures for, ensures compliance with, and assesses the effectiveness of clinical research and investigations conducted throughout Navy Medicine

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Special Assistant for Clinical Research & Director CIP -- BASIC DUTIES [slide 3]

- Represents and advocates for the Navy Medicine clinical research and CIP within DoD and the Federal medical research communities, graduate education programs and external professional associations

- Works with the Commanding Officers of the Navy Medical Regions, the Commanding Officer of NMRC, the Commander of NMLC, the CIP and GME Directors at the MTFs, and the Navy Medical Region Staffs to insure conformity to the overall BUMED strategic vision for clinical research and compliance with ALL CIP requirements and expectations

- Participates as a Member Component of the Research and Development Executive Board (REDEB)

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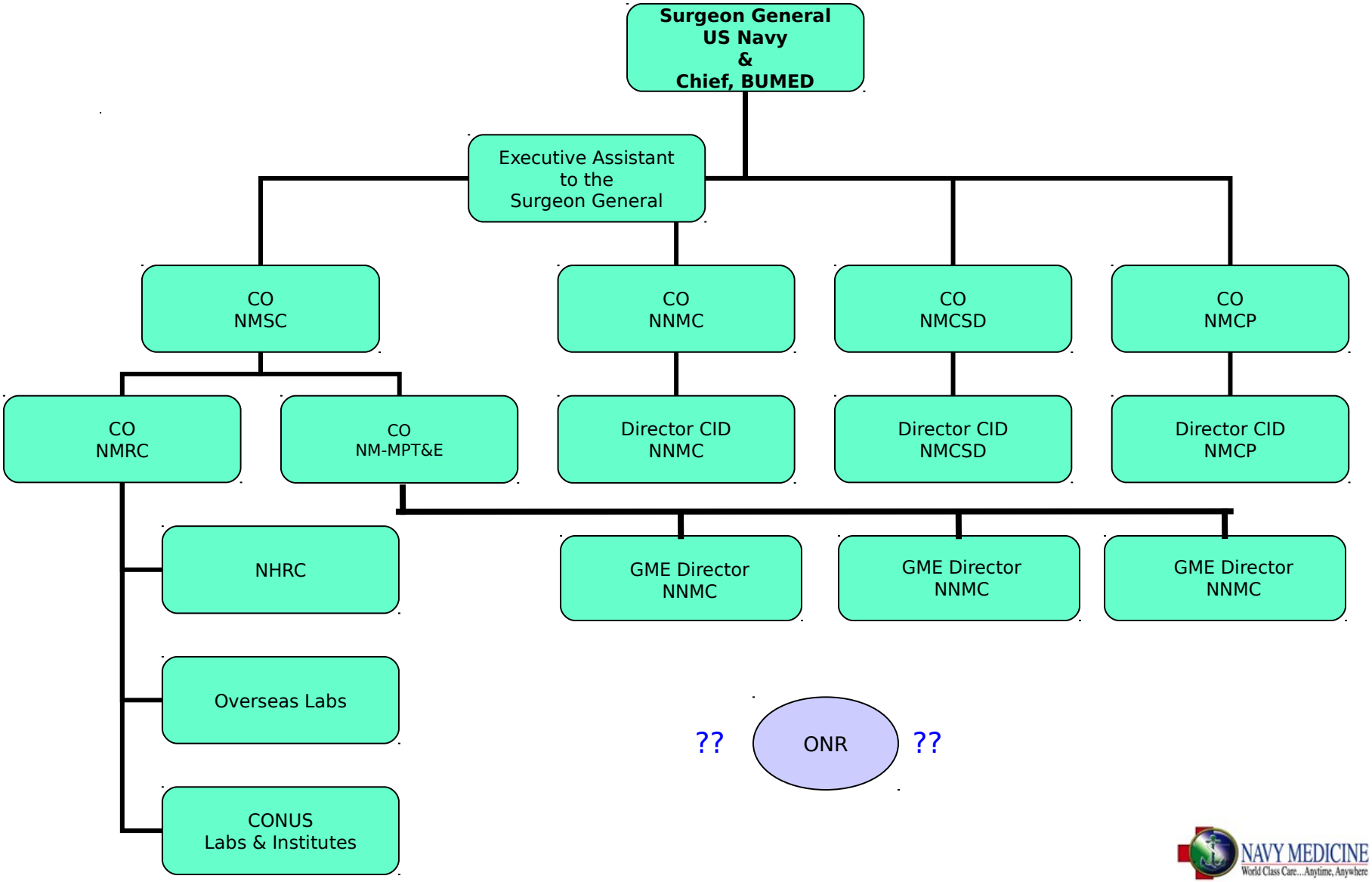
Special Assistant for Clinical Research & Director CID

Graphic for Services and Organizational Contacts



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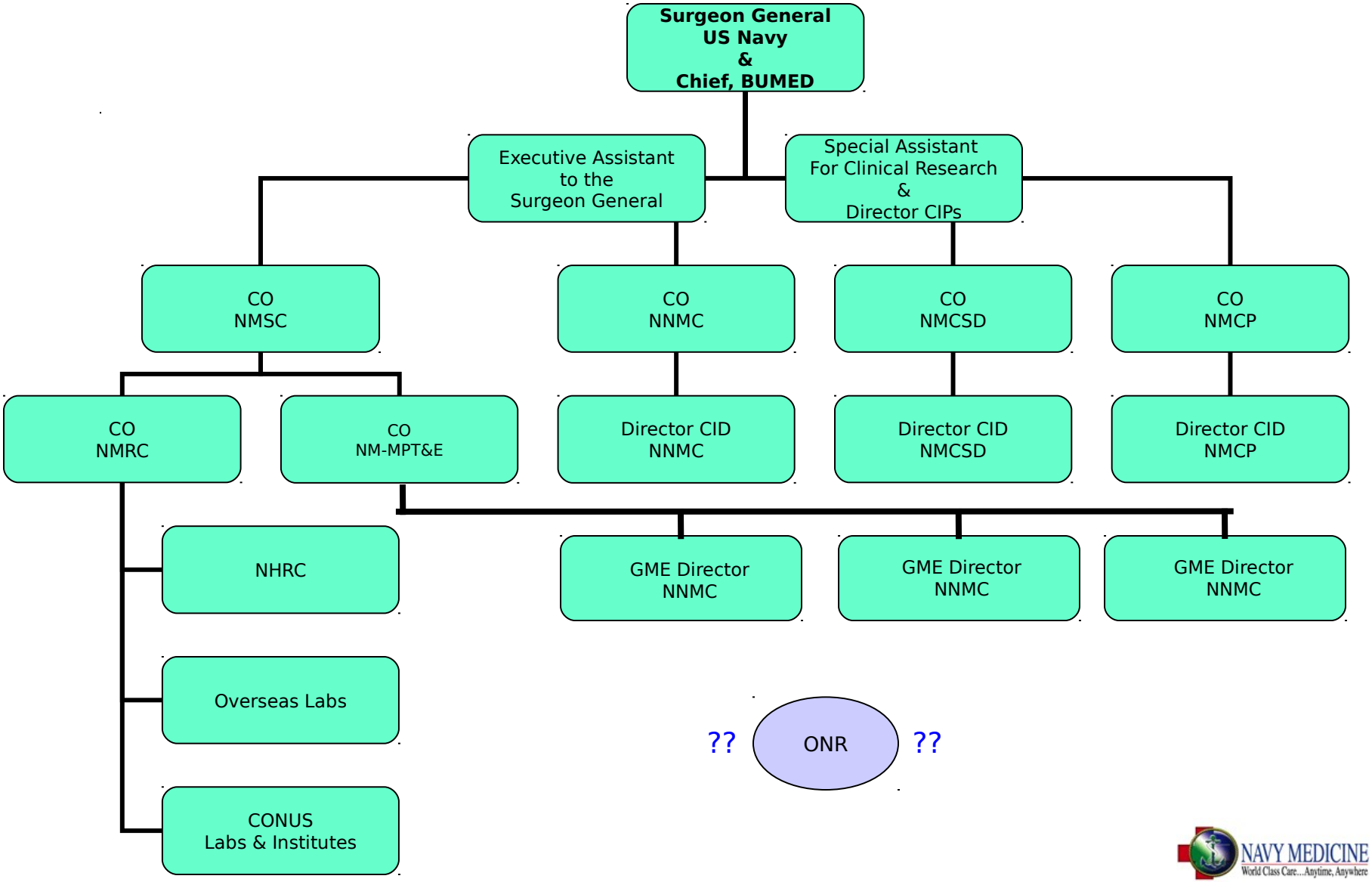

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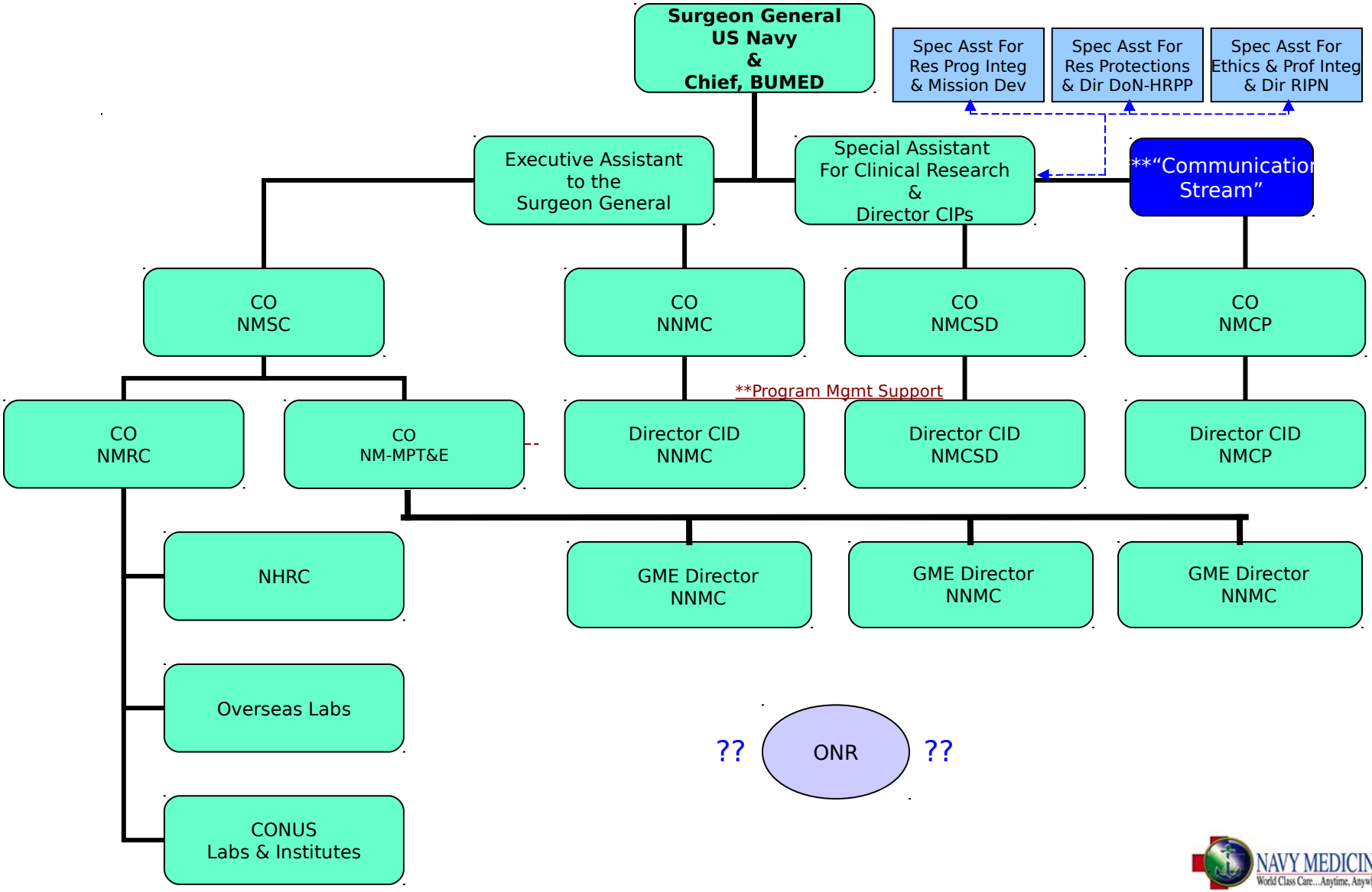

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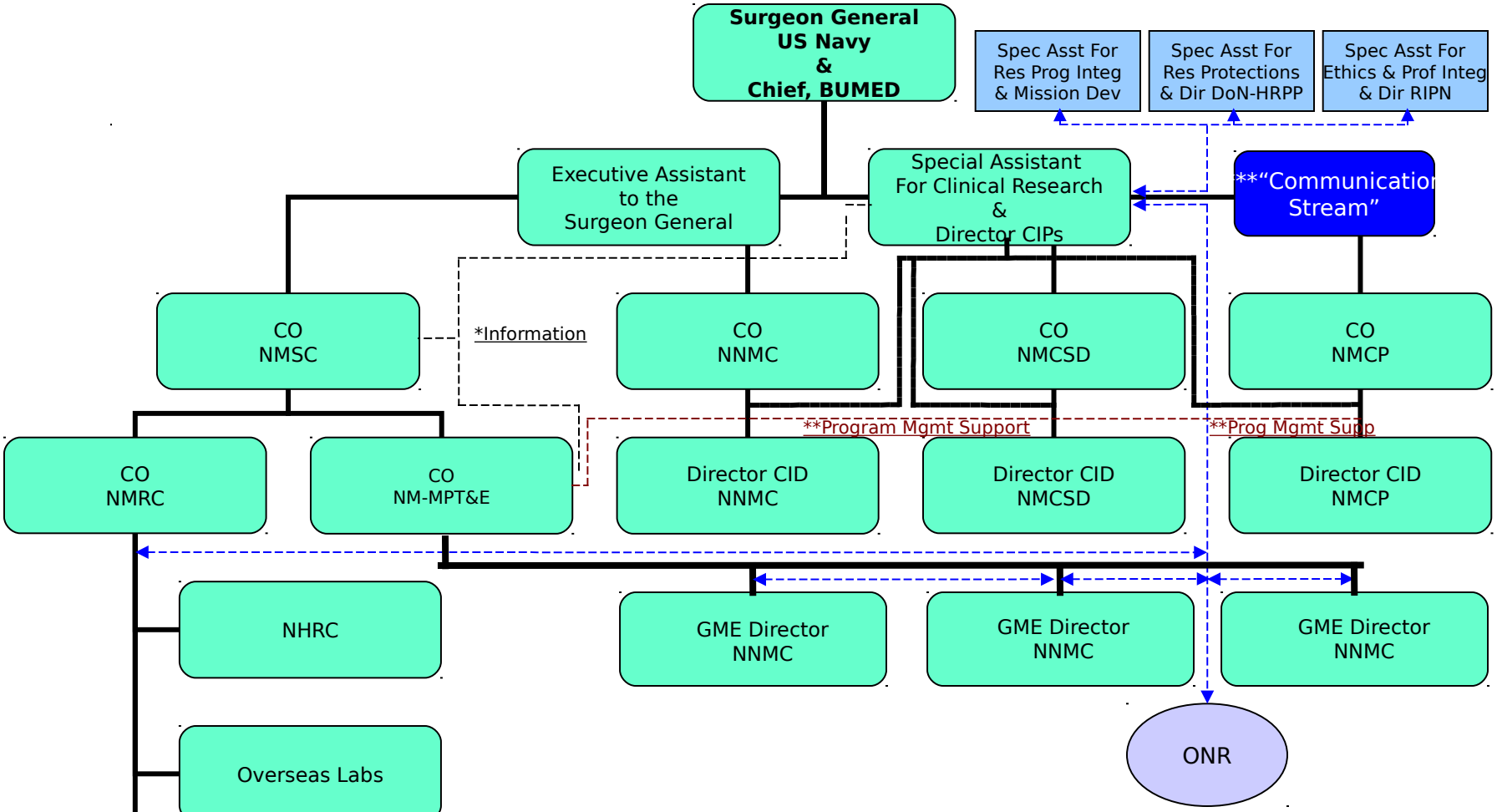

* CO NMSC/NMRC provides information on support for MTF CIP budget and logistics

** NMRC and/or NHRC supports MTF CIP budget and logistics for research projects

*** 2-way communication between GME & BUMED on clinical research support and NMRC (NHRC), ONR and BUMED on clinical research activities

Spec Asst serves in Co-reporting/Supervision chain for MTF CIP

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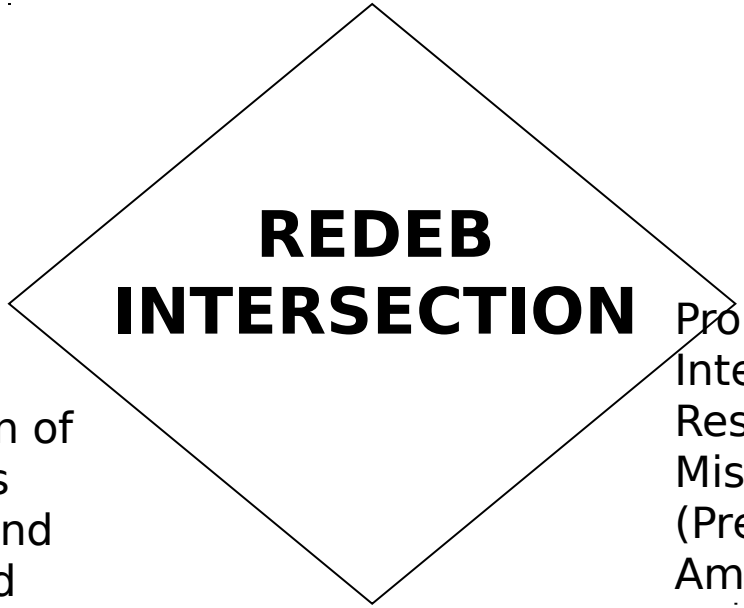
Enterprise

Emergence/Proactive: Portfolio meaning out of what is being done
Harvesting, Expand participation in R&D

Malone



Cheatham

CR/CIP

Review of tactics, utilization of resources and outcomes
Provision of professional and business tools as needed
Elevate and Promote Navy Clinical Research Internally and Externally

Gelwicks

Ethics

Promotion of Research Integrity, RCR Education, Research Misconduct/Intervention (Prevention, Correction, Amelioration), Research Admin;
Structures & Policies – Systematic Review/Eval/Update

Richard

HRP

Application of Regulation – implications as processes are established, expanding portfolio, building enterprise
Intersect – incorporate HRP into Executive Board's Work

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